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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,451	09/12/2003	Kyle Gee	MP 0075	5248

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EXAMINER	
VENCI, DAVID J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/661,451	GEE ET AL.	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *October 26, 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *8-35 and 43-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,36-42 and 48-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *September 12, 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 36-42 and 48-52, drawn to compositions and a kit comprising a fluorescent compound capable of selectively binding to an affinity tag, classified in class 435/7.7, for example.

II. Claims 8-13 drawn to a composition comprising an acetic acid binding domain capable of selectively binding to an affinity tag, classified in class 436/74, for example.

III. Claims and 43-47, drawn to a compound comprising three acetic acid groups capable of binding to an affinity tag, classified in class 514/836, for example.

IV. Claims 14-20, drawn to a method comprising the step of contacting a protein in a sample with a staining solution, classified in class 424/9.6, for example.

V. Claims 21-35, drawn to a method comprising the step of contacting an immobilized/fixed sample with a staining solution, classified in class 435/7.92, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III are related products. Related products are distinct from each other if the inventions, as claimed, are not: (1) overlapping in scope, i.e., are mutually exclusive; (2) obvious variants; and (3) capable of use together or have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j).

With respect to (1), *supra*, the inventive feature of Inventions I, II and III is a fluorescent compound. However, the scopes of Inventions I, II and III do not overlap because the fluorescent compounds are different in each Invention. For example, Inventions I requires a fluorescent compound capable of

selectively binding to an affinity tag, while Invention II requires a fluorescent compound comprising an acetic acid binding domain capable of selectively binding to an affinity tag, while Invention III requires a fluorescent compound comprising three acetic acid groups capable of binding to an affinity tag.

With respect to (2), *supra*, Inventions I, II and III are not obvious variants because each fluorescent compound of Inventions I, II and III have different physical attributes, optical characteristics, biomedical uses, etc.

With respect to (3), *supra*, Inventions I, II and III have materially different designs because Invention I requires, *inter alia*, an enzyme co-factor or prosthetic group, while Invention II requires, *inter alia*, a metal ion, while Invention III requires, *inter alia*, acetic acid groups.

With respect to Inventions I, II and III, examination burden is established because the scope of prior art search required for each Invention does not appear coextensive. For example, a search for the fluorescent compound of Invention I requires a search of prior art related to enzyme-based sensors, while a search for the acetic acid binding domain of Invention II requires a search of prior art related to radiocontrast agents, while a search for the compound comprising three acetic acid groups of Invention III requires a search of prior art related to polydentate biomolecules.

Inventions IV and V are related methods. Related methods are distinct from each other if the inventions, as claimed, are not: (1) overlapping in scope, i.e., are mutually exclusive; (2) obvious variants; and (3) capable of use together or have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j).

With respect to (1), *supra*, the inventive feature of Inventions IV and V is the step of contacting a sample with a fluorescent compound. However, the scopes of Inventions IV and V do not overlap because the samples are different in each Invention. For example, Inventions IV requires a step of contacting a protein in a sample, while Invention V requires a step of contacting an immobilized/fixed sample.

With respect to (2), *supra*, Inventions IV and V are not obvious variants because each sample of Inventions IV and V have different physical attributes, optical characteristics, biomedical uses, etc.

With respect to (3), *supra*, Inventions IV and V have materially different modes of operation because Invention IV requires, *inter alia*, a step of administering a radiocontrast agent, while Invention V requires, *inter alia*, a step of immobilizing a sample on a solid or semi-solid matrix.

With respect to Inventions IV and V, examination burden is established because the scope of prior art search required for each Invention does not appear coextensive. For example, a search for the step of contacting a sample of Invention IV requires a search of prior art related to tomography, while a search for the step of contacting a sample of Invention V requires a search of prior art related to dishes, plates, slides, strips, etc.

Inventions (I, II or III) and (IV or V) are related as products and processes of use. The inventions are distinct if either or both of the following is evident: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the products of Inventions (I, II or III) can be used in a materially different process, such as an embalming process.

As indicated, *supra*, restriction for examination purposes is proper because the inventions are distinct and require separate, non-coextensive searches of the prior art.

During a telephone conversation with Koren Anderson on June 8, 2006, Koren Anderson made a provisional election, without traverse, to prosecute the Invention I, claims 1-7, 36-42 and 48-52. Applicants must affirm this election in response to this Office action.

Claims 8-35 and 43-47 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Currently, claims 1-7, 36-42 and 48-52 are under examination.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

APPLICANT IS GIVEN ONE MONTH FROM THE DATE OF THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.F.R.. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Bio (**<http://www.uspto.gov/ebc/efs/downloads/documents.htm>**, EFS Submission User Manual - ePAVE)

2. Mailed to:

   U.S. Patent and Trademark Office
   Box Sequence, P.O. Box 2327
   Arlington, VA 22202

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 5, 6, 39, 40, 49 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 3, the phrase "A is a fluorophore" is indefinite. Whether "A is a fluorophore" references "a fluorophore" recited in claim 1 is not clear.

In claim 5, the open claim language "said fluorescent compound comprises glutathione" is indefinite in view of closed claim 3 language "said fluorescent compound is according to formula A(L)m(B)n". Whether/how "glutathione" references "formula A(L)m(B)n" is not clear.

In claim 6, the phrase "an acetic acid binding domain" is indefinite. Whether "an acetic acid binding domain" references one or more acetic acid groups and/or one or more domains capable of binding to one or more acetic acid groups is not clear.

In claim 39, the phrase "a fluorophore" is indefinite. Whether "a fluorophore" references "a fluorophore" recited in claim 36 is not clear.

In claim 40, the phrase "A is a fluorophore" is indefinite. Whether "A is a fluorophore" references "a fluorophore" recited in claim 36 is not clear.

In claim 40, the phrase "an acetic acid binding domain" is indefinite. Whether "an acetic acid binding domain" references one or more acetic acid groups and/or one or more domains capable of binding to one or more acetic acid groups is not clear. The relationship, if any, between said "acetic acid binding domain" with "at least three acetic acid groups" is not clear. Whether said "acetic acid binding domain" references "a binding domain" recited in claim 39 is not clear.

In claim 49, the phrase "a fluorophore" is indefinite. Whether "a fluorophore" references "a fluorophore" recited in claim 48 is not clear.

In claim 50, the phrase "A is a fluorophore" is indefinite. Whether "A is a fluorophore" references "a fluorophore" recited in claim 48 and/or/not claim 49 is not clear.

In claim 50, the phrase "an acetic acid binding domain" is indefinite. Whether "an acetic acid binding domain" references one or more acetic acid groups and/or one or more domains capable of binding to one or more acetic acid groups is not clear. The relationship, if any, between said "acetic acid binding domain" with "at least three acetic acid groups" is not clear. Whether said "acetic acid binding domain" references "a binding domain" recited in claim 49 is not clear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 36-39 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Majima *et al.*, 1243 BIOCHIM. BIOPHYS. ACTA 336 (1995).

Majima *et al.* describe a staining solution comprising:

(a) a fluorescent compound (see Fig. 1, "EMA"); and

(b) a buffer (see p. 337, right column, *2.5 Time-course of chemical modification...*, "100 mM phosphate buffer").

Claims 1-4, 6-7, 36-42 and 48-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Lomas (US 2003/0077616).

Lomas describes a staining solution comprising:

(a) a fluorescent compound (see Table. 1, Affinity label, "fluorescein"); and

(b) a buffer (see paragraph [0126]).

With respect to claim 48, Lomas describes a fusion protein (see *e.g.*, paragraph [0180]-[0181]).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6-7, 36-41 and 48-51 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18, 20-22 and 24 (misnumbered) of copending Application No. 10/966,536. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '536 application also claims a staining solution (see claim 18, step ii), "staining solution") comprising a fluorescent compound (see claim 20, "xanthene") and a buffer (see claim 18, step (ii)(b), "buffer").

A person of ordinary skill in the art would have recognized that the limitations of claims 1-4, 6-7, 36-41 and 48-51 of the instant application encompass the limitations of claims 18, 20-22 and 24 of copending Application No. 10/966,536.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David J Venci
Examiner
Art Unit 1641

djv

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Notice to Comply	Application No. 10/661,451	Applicant(s) Haugland et al.	
	Examiner D. Venci	Art Unit 1641	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other:

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571) 272-2510
For CRF Submission Help, call (571) 272-2501/2583.
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